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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------------|
| 10/822,303 | 04/09/2004 | Rino Rappuoli | 20480.019 | 3584 |
| <div>27476 7590 07/23/2007 NOVARTIS VACCINES AND DIAGNOSTICS INC. CORPORATE INTELLECTUAL PROPERTY R338 P.O. BOX 8097 Emeryville, CA 94662-8097</div> | | | | |
| | | | EXAMINER PENG, BO | |
| | | | ART UNIT 1648 | PAPER NUMBER |
| | | | MAIL DATE 07/23/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,303

Applicant(s)

RAPPUOLI ET AL.

Examiner

Bo Peng

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 121-126 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 121-126 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. The preliminary amendment file on April 12, 2007 is acknowledged. Claims 9-21, 24, 29-93, 99-113, 116 and 118-120 are canceled. Claims 1-8, 22, 23, 25, 27, 114, 115 and 117 are amended and Claims 121-126 have been added. Accordingly, Claims 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 121-126 are pending.

3. Applicants' election of Group I and species of SARS virus Spike (S) polypeptides, filed on April 12, 2007, is acknowledged.

4. Upon a review of the amendment, the Office has determined that a new restriction requirement is necessary as set forth below.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 94-98, drawn to a polypeptide comprising S polypeptide SEQ ID NO: 6042 and a fragment thereof, classified in class 424, subclass 184.1.
- II. Claims, 27, 28, 121 and 122, drawn to a polypeptide comprising a S polypeptide and a second SARS CoV protein, classified in class 424, subclass 184.1.
- III. Claims 123, drawn to a polypeptide comprising a S polypeptide and a second non-

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SARS CoV protein, classified in class 424, subclass 184.1.

IV. Claims 124-126, drawn to a polypeptide comprising a S polypeptide and a bacterial protein, classified in class 424, subclass 184.1.

6. Groups I-IV are different products. Groups I-IV are directed to patentably distinct polypeptides, wherein each has a different structure and biological property, and wherein each is capable of separate manufacture and use.

7. Claims 1-8, 22, 23, 25, 26, 114, 115 and 117 are linking claims, which link Group II, III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 1-8, 22, 23, 25, 26, 114, 115 and 117. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

8. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170

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USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. Claims 1-8 and 121-126 encompass hundreds of polypeptides SEQ ID NOs and the peptide combinations, which are considered to be unrelated for the reasons set forth below.

Applicants are required to elect a single polypeptide with SEQ ID NO: from Claims 1-8, and a single polypeptide with SEQ ID NO: from Claims 121-126 is any of corresponding Groups is elected. Please note: It is not species election.

10. The polypeptides and the peptide combinations encompassed in Claims 1-8 and 121-126 are considered to be unrelated because they do not share either a common utility or substantial structural feature essential to that utility as set forth in *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group: (1) share a common utility, and (2) share a substantial structural feature essential to that utility. In the instant case, polypeptides in the Claims 1-8 and 121-126 do not share either a common utility or substantial structural feature essential to that utility. Some polypeptides in the Claims 1-18 and 121-126 may share a common utility, but they do not meet the second prong of the test set out in *In re Harnish* (Id.) which requires that the sequences must also share a substantial structural feature disclosed as being essential to that utility. As such, each peptide is considered a patentably distinct invention. Moreover, a search and examination of hundreds peptides and peptide combinations in one application constitutes undue burden on the Office. Therefore, restriction of claimed peptides for examination purposes as indicated is proper. Applicant is advised, however, to point out other peptides in Claims 1-8 and 121-126 that share substantial

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structural feature with the elected polypeptide, which may be rejoined when the elected peptides are found to be allowable.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is required to elect ONE adjuvant, which is a detoxified bacterial ADP-ribosylating toxin, a non-toxic double mutant form of *Bordella pertussis* toxoids, chitosan, MF59, aluminium, and aluminum salt OR a SMIP (Claim 115).

13. If Group III above is elected, Applicant is required to elect ONE non-SARS virus protein that is derived from a coronavirus, influenza virus, rhinovirus, parainfluenza virus, respiratory syncytial virus, adenovirus OR metapneumovirus (Claim 123).

14. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

17. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37

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CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

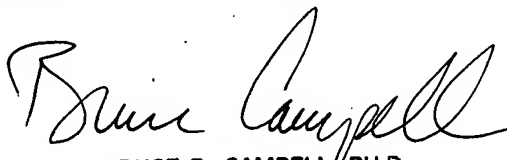
21. Applicant is reminded the upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance the 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP
Bo Peng, Ph.D.
June 25, 2007


BRUCE R. CAMPBELL, PH.D.
SUPERVISORY PATENT EXAMINER
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